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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,815	07/09/2001	Lars Lannfelt	LANNFELT1A	9645

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YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,815	LANNFELT ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-15 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *8-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 17-23 have been cancelled and claims 24-38 have been added as requested in the amendment of Paper No. 21, filed on April 21, 2003. Claims 8-15 and 24-38 are pending in the instant application.

Claims 8-15 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Claims 24-38 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on April 21, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Objections

5. Claims 24, 27 and 28 are objected to because of the following informalities: recitation "non-wildtype" appears to be either misspelled or missing support in the instant specification, as filed. For purpose of examination recitation "non-wildtype" is interpreted as "non-wild type". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 26 encompasses a methods of treatment of Alzheimer's disease with "an active fragment" of Aβ peptide. However, the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of an Aβ peptide. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are methods of using active fragments of Aβ peptide. First, the claims are not limited to a protein with a specific amino acid sequence. The claims only require the polypeptide share some degree of structural similarity to the Aβ peptide. The specification only describes a protein having the amino acid sequence of SEQ ID NO:1 and SEQ ID NO: 2 and fails to teach or describe any other protein which lacks these sequences and has the activities

possessed by the Aβ peptide. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of a representative number of species or the genus which are encompassed by the instant claim. The specification does not provide a complete structure of those active fragments of Aβ peptide. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus of active fragments of Aβ peptide. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 24-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-38 are vague and indefinite for recitation "non-wildtype protofibril". Applicant's arguments regarding definition of terms "protofibril" and "fibril" in reference to their molecular weight (page 9 of the Response) are found to be not supported by the instant specification, as filed. Therefore, the metes and bounds of the instant recitation cannot be determined from the claims or the instant specification.

Claim Rejections - 35 USC § 102

8. Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk (WO 99/27944, June 1999, Reference AD of IDS of Paper No. 12) for reasons of record as applied to claims 17, 18, 22 and 23 in section 17 of Paper No. 17. Briefly, Schenk teaches a method of preventing or treating Alzheimer's disease by administration an agent, wherein an agent includes "Aβ peptide itself and variants thereof, analogs and mimetics of Aβ peptide that induce and/or crossreact with antibodies to Aβ peptide" (page 13, last paragraph). Because the Aβ-Arc peptide of SEQ ID NO: 1 of the instant invention differs from a regular Aβ peptide only by substitution of Gly to Glu in position 22, one would readily understand that antibodies to Aβ peptide would crossreact with antibodies to Aβ-Arc peptide. Thus, Aβ disclosed in Schenk document encompasses an Arctic mutation of Aβ of the instant specification as well as "an active fragment thereof" (see claim 26).

Applicant's argument that "the SCHENK publication describes a method for the preparation of "aggregated Aβ peptides" (page 10, last paragraph and page 11 of the Response) while the instant specification discloses stable soluble protofibrils has been fully considered but is not deemed to be persuasive for the following reasons. As fully explained earlier, Aβ peptide of Schenk is an Aβ peptide itself, a 40-42 amino acid peptide or an Aβ peptide aggregate (see p.3 lines 28-29). Thus, document of Schenk encompasses both forms of Aβ peptide, soluble and aggregated.

9. Claims 27-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk (WO 99/27944, June 1999) for reasons of record as applied to claim 19 in section 18 of Paper No. 12.

Claims 27-38 are drawn to a method for prevention or treatment of Alzheimer's disease by administration of an antibody against a non- wild type protofibril.

Schenk teaches a method of treating an Alzheimer's disease by administration of an antibody to Aβ (claim 24). Because Aβ peptide of Schenk includes "Aβ peptide itself and variants thereof, analogs and mimetics of Aβ peptide that induce and/or crossreact with antibodies to Aβ peptide", antibodies to Aβ peptide of Schenk encompass antibodies against all forms of Aβ peptide, including Aβ-Arc peptide (see reasoning in section 8 earlier in the instant office action). This is also confirmed by the instant specification, see claims 27 and 29, directed to administration of antibodies against mutated form of Aβ peptide, claim 27, and wild type from of Aβ peptide, claim 29. Therefore, the disclosure of Schenk anticipates claims 27-31 and 34-36. Furthermore, the document of Schenk discloses monoclonal, human and humanized antibodies (see text on page 18). Thus, the disclosure of Schenk meets the limitations of claims 32-33 and 37-38 of the instant application.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
June 24, 2003

JOHN ULM
PRIMARY EXAMINER
GROUP 1600